IFW

PTO/SB/21 (09-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE er the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number <u>1</u>0/789,835 TRANSMITTAL Filing Date 02/27/2004 First Named Inventor **FORM** THOMPSON, Todd A. et al Art Unit N/A Examiner Name (to be used for all correspondence after initial filing) Unknown Attorney Docket Number 103 054030-0052 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Fee Transmittal Form Drawing(s) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final Proprietary Information Provisional Application Power of Attorney, Revocation Affidavits/declaration(s) Status Letter Change of Correspondence Address Other Enclosure(s) (please Identify Terminal Disclaimer Extension of Time Request below): Return Receipt Postcard Request for Refund Express Abandonment Request Letter re IDS CD, Number of CD(s) Information Disclosure Statement Transmittal Form ,4 references (96 sheets) Fee Transmittal Landscape Table on CD Certified Copy of Priority Remarks Document(s) Reply to Missing Parts/ Incomplete Application

Signature OF APPLICANT, ATTORNEY, OR AGENT

Signature Of APPLICANT, ATTORNEY, OR AGENT

Printed name Charles L. Leeck

Date 7-70-04 Reg. No. 50,343

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

Signature

Auth Clen Genar

Typed or printed name Ruth Ellen Genac

Reply to Missing Parts under 37 CFR 1.52 or 1.53

Date

09/30/2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

(\$) 0.00

TOTAL AMOUNT OF PAYMENT

FEE TRANSMITTAL	Complete if Known		
FEE INANSMITTAL	Application Number	10/789,835	
for FY 2004	Filing Date	02/27/2004	
Effective 10/01/2003. Patent fees are subject to annual revision.	First Named Inventor	THOMPSON, Todd A. et al.	
	Examiner Name	Unknown	
Applicant claims small entity status. See 37 CFR 1.27	Art Unit	N/A	

TOTAL AMOUNT OF PAYMENT (\$) 0.00 Attorney Docket No. 054030-0052					
METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)				
Check Credit card Money Other None	ne 3. ADDITIONAL FEES				
Deposit Account:	Large Entity Small Entity				
Denosit	Fee Fee Fee Fee Fee Description	- Daid			
Account 07–1509	1051 130 2051 65 Surcharge - late filing fee or oath	ee Paid			
Deposit	1052 50 2052 25 Surcharge - late provisional filing fee or				
Account Godfrey & Kahn, S.C.	cover sheet				
The Director is authorized to: (check all that apply)	1053 130 1053 130 Non-English specification 1812 2,520 1812 2,520 For filing a request for ex parte reexamination				
Charge fee(s) indicated below Credit any overpayments	1804 920* 1804 920* Requesting publication of SIR prior to				
Charge any additional fee(s) or any underpayment of fee(s)	Examiner action				
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805 1,840* 1805 1,840* Requesting publication of SIR after Examiner action				
	1251 110 2251 55 Extension for reply within first month				
FEE CALCULATION	1252 420 2252 210 Extension for reply within second month				
1. BASIC FILING FEE Large Entity Small Entity	1253 950 2253 475 Extension for reply within third month				
Fee Fee Fee Fee Description Fee Paid	1254 1,480 2254 740 Extension for reply within fourth month				
Code (\$) Code (\$) 1001 770 2001 385 Utility filing fee	1255 2,010 2255 1,005 Extension for reply within fifth month				
1002 340 2002 170 Design filing fee	1401 330 2401 165 Notice of Appeal				
1003 530 2003 265 Plant filing fee	1402 330 2402 165 Filing a brief in support of an appeal				
1004 770 2004 385 Reissue filing fee	1403 290 2403 145 Request for oral hearing				
1005 160 2005 80 Provisional filing fee	1451 1,510 1451 1,510 Petition to institute a public use proceeding				
SUBTOTAL (1) (\$)	1452 110 2452 55 Petition to revive - unavoidable				
	1453 1,330 2453 665 Petition to revive - unintentional				
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	E 1501 1,330 2501 665 Utility issue fee (or reissue)				
Extra Claims below Fee Paid	d 1502 480 2502 240 Design issue fee				
Independent	1503 640 2503 320 Plant issue fee				
Claims - 3** = X	1460 130 1460 130 Petitions to the Commissioner				
	1807 50 1807 50 Processing fee under 37 CFR 1.17(q)				
Large Entity Small Entity Fee Fee Fee Fee Fee Description	1806 180 1806 180 Submission of Information Disclosure Stmt				
Code (\$) Code (\$)	8021 40 8021 40 Recording each patent assignment per property (times number of properties)				
1202 18 2202 9 Claims in excess of 20	1809 770 2809 385 Filing a submission after final rejection				
1201 86 2201 43 Independent claims in excess of 3	(37 CFR 1.129(a))				
1203 290 2203 145 Multiple dependent claim, if not paid 1204 86 2204 43 ** Reissue independent claims	1810 770 2810 385 For each additional invention to be examined (37 CFR 1.129(b))				
1204 86 2204 43 ** Reissue independent claims over original patent	1801 770 2801 385 Request for Continued Examination (RCE)				
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent	1802 900 1802 900 Request for expedited examination of a design application				
	Other fee (specify)				
SUBTOTAL (2) (\$) **or number previously paid, if greater, For Reissues, see above	*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$)				
SUBMITTED BY	(Complete (if applicable))				

Registration No. Name (Print/Type) Telephone 50.343 Attorney/Agent) Signature

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Applicant:

Todd A. Thompson, et al.

Application No.:

10/789,835

For:

CHROMAN-DERIVED ANTI-ANDROGENS FOR

TREATMENT OF ANDROGEN-MEDIATED DISORDERS

Filed:

February 27, 2004

Group Art Unit:

N/A

Examiner:

Unknown

Attorney Docket No.:

054030-0052

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 09/30/2004 22313-1450 on_

Ruth Ellen Genac

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

Dear Sir:

In accordance with 37 C.F.R. §§ 1.56, 1.97, and 1.98, the Applicant submits the references listed below for consideration.

Non-Patent References:

BRIGELIUS-FLOHE, R. and TRABER, M.G. Vitamin E: function and metabolism. FASEB J., 13: 1145-1155, 1999.

BURTON, G.W. and TRABER, M.G. Vitamin E: antioxidant activity, biokinetics, and bioavailability. Annu. Rev. Nutr., 10: 357-382, 1990.

HOROSZEWICZ, J.S. LEONG, S.S., KAWINSKI, E., KARR, J.P., ROSENTHAL, H., CHU,

T.M., MIRAND, E.A., and MURPHY, G. LNCaP model of human prostatic carcinoma.

Cancer Res., 43: 1809-1818, 1983.

- WARRIAR, N., PAGE, N., KOUTSILIERIS, M. and GOVINDAN, M.V. Anti-androgens inhibit human androgen receptor-dependent gene transcription activation in the human prostate cancer cells LNCaP. Prostate, 24: 176-186, 1994.
- VELDSCHOLTE, J., BERREVOETS, C.A., and MULDER, E. Studies on the human prostatic cancer cell line LNCaP. J. Steroid Biochem. Mol. Biol., 49: 341-346, 1994.
- ISRAEL, K., SANDERS, B.G., and KLINE, K. RRR-α-tocopherol succinate inhibits the proliferation of human prostatic tumor cells with defective cell cycle/differentiation pathways. Nutr. Cancer, 24: 161-169, 1995.
- VENKATESWARAN, V., FLESHNER, N.E. and KLOTZ, L.H. Modulation of cell proliferation and cell cycle regulators by vitamin E in human prostate carcinoma cell lines. J. Urol., *168*: 1578-1582, 2002.
- NI, J., CHEN, M., ZHANG, Y., LI, R., HUANG, J., and YEH, S. Vitamin E succinate inhibits human prostate cancer cell growth via modulating cell cycle regulatory machinery. Biochem. Biophys. Res. Commun., 300: 357-363, 2003.
- GUNAWARDENA, K., MURRAY, D.K., and MEIKLE, A.W. Vitamin E and other antioxidants inhibit human prostate cancer cells through apoptosis. Prostate, 44: 287-295, 2000.
- ISRAEL, K., YU, W., SANDERS, B.G., and KLINE, K. Vitamin E succinate induces apoptosis in human prostate cancer cells: role for Fas in vitamin E succinate-triggered apoptosis.

 Nutr. Cancer, 36: 90-100, 2000.
- ZHANG, Y., NI, J., MESSING, E.M., CHANG, E., YANG, C.R., and YEH, S. Vitamin E succinate inhibits the function of androgen receptor and the expression of prostate-specific antigen in prostate cancer cells. Proc. Natl. Acad. Sci. U.S.A., 99: 7408-7413, 2002.

WILDING, G., CHEN, M., and GELMANN, E.P. Aberrant response *in vitro* of hormone-responsive prostate cells to anti-androgens. Prostate, *14*: 103-115, 1989.

- NAKAMURA, K., YASUNAGA, Y., SEGAWA, T., KO, D., MOUL, J.W., SRIVASTAVA, S., and RHIM, J.S. Curcumin down-regulates AR gene expression and activation in prostate cancer cells. Int. J. Oncol., *21*: 825-830, 2002.
- LE, H.T., SCHALDACH, C.M., FIRESTONE, G.L., AND BJELDANES, L.F. Plant-derived 3, 3'-diindolylmethane is a strong androgen antagonist in human prostate cancer cells. J. Biol. Chem., 278: 21136-21145, 2003.

Respectfully Submitted,

GODFREY & KAHN, S.C.

9-30-04

Attorney of Record for the Applicant GODFREY & KAHN, S.C. 780 North Water Street
Milwaukee, WI 53202-35590
(414) 273-3500
MW848359_1.DOC

By

Charles L. Leeck

Registration No. 50,343

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitut	te for form 1449/PTO			Complete if Known		
Ouboutu	101101111111111111111111111111111111111			Application Number	10/789,835	
INFO	INFORMATION DISCLOSURE		Filing Date	02/27/2004		
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	THOMPSON, Todd A.	
	(Use as many sheets as necessary)		Art Unit	N/A		
(USE as many sneets as necessary)		Examiner Name	Unknown			
Sheet	1	of	2	Attorney Docket Number	054030-0052	フ

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BRIGELIUS-FLOHE, R. et al. 1999. FASEB J. 13:1145-1155	
		BURTON, G.W. et al. 1990. Annu. Rev. Nutr., 10:357-382	
		HOROSZEWICZ, J.S. et al. 1983. Cancer Res., 43:1809-1818	
		WARRIAR, N. et al. 1994. Prostate, 24:176-186	
		VELDSCHOLTE, J. et al. 1994. J. Steroid Biochem. Mol. Biol., 49: 341-346	
		ISRAEL, K. et al. 1995. Nutr. Cancer, 24:161-169	
		VENKATESWARAN, V. et al. 2002. J. Urol., 168:1578-1582	
		NI, J. et al. 2003. Biochem. Biophys. Res. Commun., 300:357-363	
		GUNAWARDENA, K. et al. 2000. Prostate, 44:287-295	
		ISRAEL, K. et al. 2000. Nutr. Cancer, 36:90-100	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449/PTO	Complete if Known		
	Application Number	10/789,835	
INFORMATION DISCLOSURE	Filing Date	02/27/2004	
STATEMENT BY APPLICANT	T First Named Inventor THOMPSON, Todd A.		
(Use as many sheets as necessary)	Art Unit	N/A	
(ose as many shoets as necessary)	Examiner Name	Unknown	
Sheet 2 of 2	Attorney Docket Number	054030-0052	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ZHANG, Y. et al. 2002. Proc. Natl. Acad. Sci. U.S.A., 99:7408-7413	
		WILDING, G. et al. 1989. Prostate, 14:103-115	
		NAKAMURA, K. et al. 2002. Int. J. Oncol., 21:825-830	
_		LE, H.T. et al. 2003. J. Biol. Chem., 278:21136-21145	
	-		
!			

	 		
Examiner		Date	
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.